K003164
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RICHARD WOLF
Medical Instruments Corporation

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510(k) Summary of Safety and Effectiveness

Submitter			Date of this Summary: October 2, 2000
Company / Institution name: RICHARD WOLF MEDICAL INSTRUMENTS CORP.			**FDA establishment registration number:** 14 184 79
Division name (if applicable): N.A.			**Phone number (include area code):** (847) 913-1113
Street address: 353 Corporate Woods Parkway			**FAX number (include area code):** (847) 913-0924
City: Vernon Hills	**State/Province:** Illinois	**Country:** USA	**ZIP / Postal Code:** 60061
Contact name: Mr. Robert L. Casarsa			
Contact title: Quality Assurance Manager			

Product information	
Trade name: Trocars "TROTEC" with automatic mechanism	**Model number:** Various part numbers of trocars, ... see section 4: 'submitted devices'
Common name: Trocars with automatic mechanism	**Classification name:** Trocar, Gastro-urology

Information on devices to which substantial equivalence is claimed:

510(k) Number	Trade or proprietary or model name	Manufacturer
1 K960299	1 Pyramidal Trocar with spring-return protective sleeve	1 Richard Wolf
2	2 Safety Trocar	2 Pajunk
3	3 Endopath TRISTAR Trocar	3 Ethicon
4	4 Sensing tip trocar	4 Origin

1.0 Description

The submitted TROTEC Trocars consist of sheath with trocar tip and a grip with spring loaded rod. The automatic mechanism shields the trocar tip when in a locked position.

2.0 Intended Use

TROTEC trocars intended use is to establish intra-abdominal access to facilitate the insertion of cannula through the abdominal wall.

3.0 Technological Characteristics

The shielding mechanism in the submitted devices functions (locks in position) at an early stage, specifically, when the abdominal wall is penetrated and a large part of the trocar tip is still inside the abdominal wall. The shielding mechanism engages automatically.

4.0 Substantial Equivalence

The submitted devices pose the same type of questions about safety or effectiveness as the compared devices. The new technological characteristics have not diminished safety or effectiveness. The submitted devices are substantially equivalent to existing 510(k) devices sold by Richard Wolf, Origin, Ethicon or Pajunk.

5.0 Performance Data

No performance standards are known.

6.0 Clinical Tests

Clinical tests were not performed.

7.0 Conclusions

These devices are designed and tested to assure their safety and effectiveness when used according to the instructions manual.

By: Robert L. Casarsa Date: Nov 27, 2000

Robert L. Casarsa
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 8 2001

Mr. Robert L. Casarsa
Quality Assurance Manager
Richard Wolf Medical Instruments Corporation
353 Corporate Woods Parkway
VERNON HILLS IL 60061

Re: K003164
"TROTEC" Shielded Trocars
Dated: October 9, 2000
Received: October 10, 2000
Regulatory Class: II
21 CFR §884.1720/Procode: 85 HET

Dear Mr. Casarsa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

[redacted]

510(k) Number (if known): K003164

Device Name: Trocars " TROTEC' with automatic shielding mechanism

Intended Use:

The TROTEC Trocar is intended to establish intra-abdominal access to facilitate the insertion of cannula through the abdominal wall.

Indications and Application:

The TROTEC Trocar is designed for diagnostic and operating procedures in conjunction with the appropriate accessory instruments. The procedure must be performed by adequately trained and qualified medical personnel.

Contraindications:

Contraindications directed related to the product are presently unknown. The attending physician must decide if the intervention is appropriate.

Combinations:

TROTEC trocars may only be used in combination with RIWO-ART trocar sleeves manufactured by Richard Wolf.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

David G. Segner

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003164

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter